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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,364	07/19/2000	Nathaniel Heintz	600-1-192N2	2192

7590

04/18/2003

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/18/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/619,364

Applicant(s)

HEINTZ ET AL.

Examiner

Gerald G Leffers Jr.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 33-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-18, 20, 25-27, 29 and 48 is/are rejected.
- 7) ☒ Claim(s) 21-24, 28 and 30-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 2/11/03 as Paper No. 17, in which several claims were amended (claims 15-16, 18 and 20) and in which new claim 48 was added. Claims 1-18, 20-48 are pending in the instant application, with claims 1-14 and 33-47 withdrawn from consideration as being directed to nonelected inventions.

Any rejection of record in the previous office action not addressed herein is withdrawn. This action is not final as there is at least one grounds of rejection made herein that was not necessitated by applicants' amendment of the claims in Paper No. 17.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection.**

Claim 27 recites the limitation "wherein the two homologous nucleotide sequences are IRESEGFP". The term "IRESEGFP" appears to refer to an internal ribosome entry site (IRES) sequence operatively linked to a nucleotide sequence encoding an enhanced green fluorescence protein (EGFP). The exact nucleotide sequence encompassed by this term is not described in the instant application and does not appear to be a consensus sequence known in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-18, 20, 25-26, 29, and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-7 of U.S. Patent No. 6,485,912. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The rejected claims from the instant application are directed towards a general method of selectively performing homologous recombination with a particular nucleotide sequence present on a Bacterial or Bacteriophage-Derived Artificial Chromosome (BBPAC). The methods comprise the use of a recombination-deficient host cell and a conditional replication shuttle vector, where the shuttle vector encodes a protein that mediates recombination between the particular nucleotide sequence on the BBPAC and a homologous sequence on the shuttle vector. Optionally, the cells are grown under conditions wherein the expression of the gene encoding the recombinase is transient due to the inability of the shuttle vector comprising the recombinase gene to replicate in the host cell.

The claims of the '912 patent are drawn towards a specific embodiment which meets each of the instant claim limitations and which anticipate the instant claims. In the claims of the '912 patent, the shuttle vector carries a eukaryotic promoter exon/intron unit (PEU) that is introduced into the BBPAC. Therefore, the species claims of the '912 patent necessarily make obvious the rejected claims from the instant application. Moreover, if a patent were to issue on the instant claims, possible harassment by multiple assignees could, improperly, result.

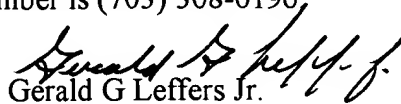
Conclusion

Claims 1-18, 20-48 are pending in the instant application, with claims 1-14 and 33-47 withdrawn from consideration as being directed to nonelected inventions. Claims 15-18, 20, 25-27, 29, and 48 are rejected. Claims 21-24, 28, 30-32 are objected to as being dependent upon a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636